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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,504	12/19/2005	Julia Cianci	Q88025	6545

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EXAMINER	
PESELEV, ELLI	

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
05/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/536,504	CIANCI ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7-9,11-20,23-28,30-32,37 and 106* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7-9,11-20,23-28,30-32 and 37* is/are rejected.

7)☒ Claim(s) *106* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 24, 2009 has been entered.

Claims 28 and 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

A conclusion of lack of enablement means that based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims.

On page 29 of the specification, lines 1-6, it is stated that the term "treatment" encompasses prophylactic effect in terms of completely or partially preventing a microbial infection.

The broadest reasonable interpretation of the term infection merely requires that one microorganism gain entry into the cells of a host. There is no evidence that entry would be prevented.

(B) The amount of direction provided the inventor.

The data directed to the treatment of bacterial infections is clearly not commensurate with the full scope of the claimed invention.

(C) No examples directed to the prophylactic treatment of the bacterial infections has been presented.

Claims 1, 7-9, 11-20, 23-28, 30-32 and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for tobramycin prodrugs having structural formulae as set forth in Tables 2-3 of the specification, does not reasonably provide enablement for the tobramymin prodrugs encompasses by the present claims.. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

A conclusion of lack of enablement means that, based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

(A) The breadth of the claims.

The claims encompass an enormous number of possible tobramycin prodrugs.

(B) The state of the prior art.

Shechter et al (J. Med. Chem. 2002, 45, 4264-4270) disclose N-[2-sulfo0-9-fluorenylmethoxycarbonyl]3-gentamicin C1 prodrug.

(C) The level of predictability in the art.

The art of making specific prodrugs which have the desired properties and activity is highly unpredictable.

(D) The existence of working examples.

The working examples are limited to a number of specific tobramycin prodrugs set forth in Tables 2-3 of the specification.

(E) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Because there is no way to predict a priori which other prodrugs, besides those specifically disclosed, will produce an antibiotic having desired activity and/or properties, it would take an enormous amount of trial and error to test various prodrugs encompassed by the present claims.

Applicant's arguments filed March 24, 2009 have been fully considered but they are not persuasive. It has been noted that claim 1 has been amended to further define the linker group L, the pharmacokinetic group Y, and the point of attachment of the pharmacokinetic group T to tobramycin. However, note that the terminology such as esters, amides, imines, etc., are not limited to any specific structural formulas or to any number of compounds. The term "comprising" renders the terminology "a pharmacokinetic regulator comprising a hydrophobic moiety selected from..." is open-ended. There is no upper limit in the terminology "n is an integer of 1 or greater". Further, the claims sill encompass an enormous number of possible prodrugs and it would still an undue amount of trial and error to test said prodrugs.

Claims 1, 7-9, 11-20, 23-28, 30-32 and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "derivative" (claim 1, last line) renders the claims indefinite in the it is not clear what is encompassed by said term i.e. the metes and scope of the claimed invention cannot be determined.

Claim 24 is indefinite in that it depends from the cancelled claim 22.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7-9, 11-17, 19, 20, 23, 24 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Naito et al (U.S. Patent No. 3,872,079).

Naito et al disclose the claimed tobramycin derivatives (column 2) which possess antibacterial activity (column 12).

Claim 106 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev
/Elli Peselev/
Primary Examiner, Art Unit 1623